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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,685	03/09/2004	Peter M. Bonutti	782-A04-026	4865
33771	7590	04/25/2007	EXAMINER	
PAUL D. BIANCO: FLEIT, KAIN, GIBBONS, GUTMAN, BONGINI, & BIANCO P.L. 21355 EAST DIXIE HIGHWAY SUITE 115 MIAMI, FL 33180			WOO, JULIAN W	
			ART UNIT	PAPER NUMBER
			3731	
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	04/25/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/797,685	BONUTTI ET AL.	
	Examiner	Art Unit	
	Julian W. Woo	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 February 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-8 and 10-36 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 16 and 36 is/are allowed.
- 6) Claim(s) 1-6, 10-15, 17-22, 27-33 and 35 is/are rejected.
- 7) Claim(s) 7, 8, 23-26 and 34 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 11, 12, 15, 17-22, 27, 28, 30, 33, and 35 rejected under 35 U.S.C. 102(b) as being anticipated by Mollenauer et al. (6,077,277). Mollenauer et al. disclose, at least in figures 1 and 6-10 and in col. 5, line 5 to col. 6, line 21; a surgical device for attaching a retainer (76) to a suture (75), where the device includes a first member (54) including a first compression element (61), a second member (55) including a second compression element (56) that is movable in relation with the first member from a first position (see fig. 8) to a second position (see fig. 9), a suture tensioner (8) configured to receive the suture and maintain substantially constant tension on the suture through the retainer (and along with the retainer), and an external energy source (electrical power via 21 or 25), where the first and second compression elements are configured to receive the retainer; where the second member comprises a tubular section with proximal and distal ends, the proximal end including a gapped portion (58) integrated with the second compression element; where the second member comprises an actuation member (67), where the suture tensioner comprises a suture bias member (9), where the second member is removably attachable to the first member (at assembly or disassembly of the device), where the energy is contact

heating energy, where the device includes a handle assembly (at 67) and a controller assembly (62), where the handle assembly includes a handle portion (67) and an end effector (56) with a tip portion for transmitting energy to the retainer, where the controller assembly includes a controller (65) and a tubular section (54) having an end portion configured for receiving the retainer (at 61), where the handle assembly (at 67) is slidably positionable through the controller assembly, where the tip portion of the end effector comprises a protrusion (56), where the end portion of the tubular section is configured to capture a second section of the retainer, and where the suture tensioner is positioned on the tubular section (e.g., at slot 58). With respect to claims 3-5, the device is deemed to have element 55 as a first member that is positioned through a tubular section of the second member (54), where the second compression element (61) is configured to receive a first portion of the retainer, preventing movement of the first portion of the retainer (at compression); and where the first compressive element is configured to capture a second portion of the retainer, such that the second portion is separate from the first portion (i.e., strands of the retainer are separate before heating) when the second member is moved from the first position to the second position.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 10 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mollenauer et al. Mollenauer et al. disclose the invention substantially as claimed. Mollenauer et al. disclose that the bias member is used to snare a suture and impart tension on the suture upon proximal movement of the bias member, but they do not disclose that the bias member imparts tension of between 2 lbs. to 10 lbs. on the suture. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the bias member, so that it imparts a tension as claimed, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

4. Claims 13, 14, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mollenauer et al. in view of Bregen et al. (5,306,280). Mollenauer et al. disclose the invention substantially as claimed, but do not disclose an internal energy source disposed within a handle portion of the first member, where the internal energy source is a rechargeable battery. Bregen et al. teach, at least in figure 4 and in col. 5, lines 57-68, a similar surgical device having an internal energy source disposed within a

handle portion, where the energy source is a rechargeable battery (39). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Bregen et al., to modify the device of Mollenauer et al. so that it has an internal energy source that is a rechargeable battery. Such a source would allow portability of the device during its use without any physical interference from an attached power cord.

Allowable Subject Matter

5. Claims 16 and 36 are allowed.
6. Claims 7, 8, 23-26, and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
7. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a surgical device including, *inter alia*, a first and second members with first and second compression elements, a suture tensioner, an energy source, a handle assembly, and a controller assembly; where the second member includes a tubular section, a gapped portion, and an actuation member including a retainer bias member biasing the tubular section into a first position, where the first member is configured to transmit at least two different types of energy from the energy source, and where a controller of the controller assembly includes a latch for removable attaching of the controller to the handle.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

8. The claim objections and rejections under 35 U.S.C. 112, 2nd paragraph are hereby withdrawn.

Applicant's arguments regarding the rejection of claims based on the Mollenauer reference have been fully considered but they are not persuasive: See the restatement of the rejection above. With respect to arguments regarding Mollenauer's alleged failure to disclose a suture tensioner with a suture bias member (i.e., a snare including a bias member): The Examiner respectfully disagrees. That is, the Examiner has deemed the snaring portion 9 to be the suture bias member, where the snaring portion includes two resilient branches for grasping, compressing, and twisting of suture—actions which inherently effect tension in a suture held by the branches.

The Applicant has also alleged that Mollenauer fails to disclose jaws applying heat for the attachment of a retainer to suture. On the contrary, Mollenauer discloses, in col. 6, lines 4-13; that heat is applied to the retainer (76) and the suture (75), where upon melting of the suture, suture material "flows through the porous sheath [i.e., the retainer]" and flows into melted suture material from an adjoining suture segment. Thus, the retainer is attached to and even enmeshed with the suture.

Finally, the Applicant has alleged that Mollenauer fails to disclose a suture tensioner, which maintains a substantially constant tension on the suture through a

retainer or “constant tension on the meltable cores [sic] with respect to the non-meltable sheath.” Firstly, the limitation on which the Applicant relies (i.e., constant tension on a suture “with respect to” the retainer) is not necessarily stated in the claims. The claims have been given their broadest reasonable interpretation: As Mollenauer has disclosed in col. 5, lines 50-57 and as the Applicant has argued, tension is applied to the suture (75) and the retainer (76) “simultaneously.” Thus, tension is present and maintained on the suture through the retainer (as claimed), as well as on the retainer.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-

4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

April 19, 2007